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108TH CONGRESS
2D SESSION

H. R. 4899

To amend the Public Health Service Act and the Internal Revenue Code of 1986 to require agreements regarding the wholesale price of brand-name prescription drugs as a condition of the allowance of certain tax deductions and credits.

IN THE HOUSE OF REPRESENTATIVES

JULY 22, 2004

Mr. BROWN of Ohio introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Public Health Service Act and the Internal Revenue Code of 1986 to require agreements regarding the wholesale price of brand-name prescription drugs as a condition of the allowance of certain tax deductions and credits.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Sustainable Drug Pricing Act''.

SEC. 2. AGREEMENTS REGARDING PRICES OF BRAND-NAME PRESCRIPTION DRUGS; RELATION TO CERTAIN TAX DEDUCTIONS AND CREDITS.

Part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) is amended by adding at the end the following subpart:

"Subpart XI—Sustainable Drug Pricing

"SEC. 340H. AGREEMENTS REGARDING PRICES OF BRAND-NAME PRESCRIPTION DRUGS; RELATION TO CERTAIN TAX DEDUCTIONS AND CREDITS.

''(a) IN GENERAL.—

''(1) AGREEMENT.—The Secretary may in accordance with this section enter into an agreement with any manufacturer of a brand-name prescription drug for purposes of—

''(A) section 280I of the Internal Revenue Code of 1986 (relating to the allowance of a deduction for expenditures relating to the advertising, promoting, or marketing of such drug); and

''(B) section 901(l) of such Code (relating to the allowance of a foreign tax credit for income, war profits, or excess profits taxes paid or accrued with respect to such drug).

''(2) COORDINATION WITH TAX PROVISIONS.—For purposes of the provisions of the Internal Rev-

enue Code of 1986 referred to in paragraph (1), an agreement under this section shall be considered to be in effect with respect to a brand-name prescription drug unless the Secretary transmits to the Secretary of the Treasury a notice in writing that such an agreement is not in effect.

''(3) NEGOTIATIONS.—The Secretary shall negotiate with any manufacturer of a brand-name prescription drug that in good faith seeks an agreement under paragraph (1), and shall make reasonable efforts to enter into such an agreement with the manufacturer.

''(b) PUBLIC HEALTH OBJECTIVES OF AGREEMENT.—The purpose of an agreement under subsection (a) regarding a drug is to establish the maximum price at which the drug may be sold at wholesale under the agreement, reasonably taking into account—

''(1) the affordability of the drug in relation to the public-health need for the drug; and

''(2) the need for the manufacturer to invest in research and development activities toward the development of new drugs that will benefit the public health.

''(c) DURATION OF AGREEMENT; RENEGOTIATION.—

''(1) IN GENERAL.—With respect to taxable years of a manufacturer, the Secretary may enter into an agreement under subsection (a) regarding a drug only if the agreement contains provisions in accordance with the following:

''(A) In the case of the agreement as first in effect, the agreement will be in effect for not fewer than four successive taxable years.

''(B) In the case of taxable years following such four taxable years, the agreement may be periodically renegotiated at the initiative of the manufacturer or the Secretary, except that any agreement that takes effect pursuant to such a renegotiation will remain in effect for not fewer than four taxable years.

''(C) Each agreement will apply to the entirety of the taxable years with which the agreement is concerned, except that in the case of the taxable year during which the drug first enters the commercial market, the applicability of the agreement will begin on the date during the taxable year on which commercial marketing of the drug begins.

''(2) VARIATION IN MAXIMUM PRICE UNDER AGREEMENT.—With respect to the maximum price

established for a drug under an agreement under subsection (a), this section may not be construed as requiring that the agreement provide that a single maximum price be in effect throughout the taxable years with which the agreement is concerned. The maximum price may vary under the agreement according to the terms of the agreement.

''(d) VIOLATION OF AGREEMENT; LIQUIDATED PENALTY.—

''(1) IN GENERAL.—The Secretary may enter into an agreement under subsection (a) regarding a drug only if—

''(A) the agreement specifies the amount that, as a liquidated penalty, the Secretary may require the manufacturer involved to pay to the United States for failing to maintain substantial compliance with the agreement; and

''(B) such amount is sufficient to deter violations of the agreement.

''(2) HEARING; LOSS OF EFFECTIVE STATUS OF AGREEMENT.—

''(A) HEARING.—If, after providing notice and an opportunity for a hearing, the Secretary determines that a manufacturer has failed to maintain substantial compliance with the agree-

ment under subsection (a), the Secretary shall order the manufacturer—

"(i) to pay to the United States an amount as a penalty for such failure, which amount does not exceed the amount specified under paragraph (1)(A) as a liquidated penalty; and

"(ii) to take appropriate action to bring the manufacturer into compliance with the agreement.

"(B) LOSS OF EFFECTIVE STATUS.—If a manufacturer fails to comply with an order under subparagraph (A), the Secretary may transmit to the Secretary of the Treasury a notice in writing that an agreement under this section is not in effect with respect to the brand-name prescription drug involved.

"(e) GENERAL PROVISIONS.—

"(1) INDIVIDUAL DRUG AGREEMENTS.—The Secretary shall ensure that each agreement under subsection (a) concerns only one brand-name prescription drug.

"(2) MONITORING OF COMPLIANCE.—With respect to brand-name prescription drugs for which agreements under subsection (a) are in effect, the

Secretary shall monitor the prices at which such drugs are being sold and determine whether the manufacturers involved are in compliance with the agreements. The Secretary may require, as a condition of a entering into an agreement under subsection (a) with a manufacturer, that the agreement include provisions regarding the cooperation of the manufacturer with such monitoring of prices.

''(3) ACCESS TO RECORDS.—The Secretary may require, as a condition of a entering into an agreement under subsection (a) with a manufacturer, that the manufacturer provide the Secretary, during negotiations and after the agreement is made, with access to financial records of the manufacturer that relate to the brand-name prescription drug involved.

''(4) CONSIDERATION OF COMPLIANCE RECORD.—In determining to what extent to establish requirements under paragraphs (2) and (3) with respect to an agreement under subsection (a) with a manufacturer, the Secretary shall take into account whether the manufacturer has maintained substantial compliance with any other agreements under such subsection that have been made by the manufacturer.

''(f) ADVISORY PANEL ON DRUG-PRICE NEGOTIATIONS.—

''(1) IN GENERAL.—The Secretary shall establish an advisory panel to be known as the Advisory Panel on Drug-Price Negotiations (in this subsection referred to as the 'Advisory Panel').

''(2) DUTIES.—The Advisory Panel shall provide advice to the Secretary on establishing prices for the sale of brand-name prescription drugs at wholesale under agreements under subsection (a). Not later than one year after the date on which the initial appointments to the Advisory Panel under paragraph (3) are completed, the Panel shall—

''(A) select, from brand-name prescription drugs in commercial distribution as of the date of the enactment of the Sustainable Drug Pricing Act—

''(i) a list of 25 drugs that the Panel considers important to the public health; and

''(ii) a list of the 25 most commonly prescribed drugs in the United States, exclusive of drugs included on the list under clause (i); and

"(B) submit to the Secretary the recommendations of the Panel with respect to such prices for drugs on the lists.

"(3) COMPOSITION.—The Advisory Panel shall be composed of five members appointed by the Secretary from among individuals who are not officers or employees of the Federal Government. Of such members—

"(A) one shall be a representative of the pharmaceutical industry;

"(B) one shall be a representative of retail consumers generally;

"(C) one shall be a representative of retail consumers who are members of racial or ethnic minority groups;

"(D) one shall be an academic with expertise in health care economics; and

"(E) one shall be an academic with expertise in public health.

The Secretary shall appoint the initial members of the Advisory Panel not later than 180 days after the date of the enactment of the Sustainable Drug Pricing Act.

''(4) CHAIR.—The Advisory Panel shall select, by recorded vote, a member of the Panel to serve as the chair of the Panel.

''(5) TERMS.—

''(A) IN GENERAL.—Each member of the Advisory Panel shall be appointed for a term of four years, except that the term of each of the initial members expires December 31, 2007.

''(B) SERVICE AFTER EXPIRATION OF TERM.—A member of the Advisory Panel may continue to serve after the expiration of the term of the member until a successor is appointed.

''(6) VACANCIES.—

''(A) AUTHORITY OF ADVISORY PANEL.—A vacancy in the membership of the Advisory Panel does not affect the power of the remaining members to carry out the duties of the Panel.

''(B) APPOINTMENT OF SUCCESSORS.—A vacancy in the membership of the Advisory Panel shall be filled in the manner in which the original appointment was made.

''(C) INCOMPLETE TERM.—If a member of the Advisory Panel does not serve the full term

under paragraph (5)(A), the Secretary, not later than 30 days after the date on which the vacancy occurs, shall appoint an individual to serve as a member of the Advisory Panel for the remainder of such term.

''(g) DEFINITIONS.—For purposes of this section:

''(1) The term 'brand-name prescription drug' means a drug meeting each of the following criteria:

''(A) An approved application under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act is in effect for the drug, or in the case of a drug that is a biological product, a biologics license is in effect for the drug under section 351 of this Act.

''(B) The drug is subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act.

''(C) A period of market exclusivity is in effect with respect to the drug pursuant to a patent or pursuant to section 505(j) or 505A of such Act.

''(2) The term 'drug' has the meaning given such term in section 201(g)(1) of such Act.''.

SEC. 3. DENIAL OF CERTAIN TAX BENEFITS UNLESS UNLESS PRICING AGREEMENT FOR BRAND-NAME PRESCRIPTION DRUGS IS IN EFFECT.

(a) DEDUCTIONS FOR ADVERTISING.—

(1) IN GENERAL.—Part IX of subchapter B of chapter 1 of subtitle A of the Internal Revenue Code of 1986 (relating to items not deductible) is amended by adding at the end the following:

"SEC. 280I. DENIAL OF DEDUCTIONS FOR ADVERTISING FOR BRAND-NAME PRESCRIPTION DRUGS UNLESS PRICING AGREEMENT IS IN EFFECT.

''(a) IN GENERAL.—No deduction shall be allowed under this chapter for any taxable year for any expenditure relating to the advertising, promoting, or marketing (in any medium) of any brand-name prescription drug manufactured by the taxpayer.

''(b) EXCEPTION FOR QUALIFIED PRICING AGREEMENT.—

''(1) IN GENERAL.—Subsection (a) shall not apply with respect to any brand-name prescription drug for a taxable year if there is in effect for the entire taxable year a qualified pricing agreement with respect to such drug.

''(2) SPECIAL RULE REGARDING INITIAL COMMERCIAL MARKETING.—In the case of the taxable year during which a brand-name prescription drug

first enters the commercial market, subsection (a) shall not apply with respect to such drug for such taxable year if a qualified pricing agreement with respect to the drug is in effect on the date of such entry and remains in effect throughout the remainder of such year.

''(c) DEFINITIONS.—For purposes of this section—

''(1) QUALIFIED PRICING AGREEMENT.—The term 'qualified pricing agreement' means an agreement entered into under section 340H of the Public Health Service Act.

''(2) BRAND-NAME PRESCRIPTION DRUG.—The term 'brand-name prescription drug' has the meaning given such term in section 340H of the Public Health Service Act.

''(d) AGGREGATION RULES.—For purposes of this section, all members of the same controlled group of corporations (within the meaning of section 52(a)) and all persons under common control (within the meaning of section 52(b)) shall be treated as 1 person.''.

(2) CLERICAL AMENDMENT.—The table of sections for such part IX is amended by adding after the item relating to section 280H the following:

''280I. Denial of deductions for advertising for brand-name prescription drugs unless pricing agreement is in effect.''.

(b) FOREIGN TAX CREDIT.—Section 901 of such Code (relating to taxes of foreign countries and of possessions of United States) is amended by redesignating subsection (l) as subsection (m) and by inserting after subsection (k) the following new subsection:

''(l) DENIAL OF FOREIGN TAX CREDIT, ETC. WITH RESPECT TO BRAND-NAME PRESCRIPTION DRUGS UNLESS PRICING AGREEMENT IS IN EFFECT.—

''(1) IN GENERAL.—Notwithstanding any other provision of this part, no credit shall be allowed under subsection (a) for any income, war profits, or excess profits taxes paid or accrued (or deemed paid under section 902 or 960) with respect to any brand-name prescription drug manufactured by the taxpayer.

''(2) EXCEPTION FOR QUALIFIED PRICING AGREEMENT.——

''(A) IN GENERAL.—Paragraph (1) shall not apply with respect to any brand-name prescription drug for a taxable year if there is in effect for the entire taxable year a qualified pricing agreement with respect to such drug.

''(B) SPECIAL RULE REGARDING INITIAL COMMERCIAL MARKETING.—In the case of the taxable year during which a brand-name pre-

scription drug first enters the commercial market, paragraph (1) shall not apply with respect to such drug for such taxable year if a qualified pricing agreement with respect to the drug is in effect on the date of such entry and remains in effect throughout the remainder of such year.

''(3) DEFINITIONS.—For purposes of this subsection, the terms 'qualified pricing agreement' and 'brand-name prescription drug' have the meanings given such terms by section 280I.

''(4) AGGREGATION RULES.—For purposes of this subsection, a rule similar to the rule of section 280I(d) shall apply. ''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2005.

SEC. 4. FEDERAL REGISTER NOTICE.

Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a notice that informs manufacturers of brand-name prescription drugs of the provisions of the amendments made by this Act, and that invites the manufacturers to enter into negotiations with the Secretary for purposes of entering into

agreements under section 340H of the Public Health Service Act.

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